

## ALLERGEN PRODUCTS

### CHECKLIST FOR VERIFICATION OF INFORMATION TO BE PROVIDED BY APPLICATION AT CDSCO *General Information for allergen products:*

#### *Additional information to be furnished for in vitro & in vivo Allergen Products (See Overleaf)*

1	Name & Address of Manufacturer/ Importer		
2	Product details <ul style="list-style-type: none"> <li>• Name</li> <li>• Brand Name</li> <li>• Batch No/ Lot No.</li> <li>• Date of Expiry</li> </ul>		
3	Intended Use	<i>In vitro</i>	<i>In-vivo</i>
		1. Diagnostic 2. R & D	1. Diagnostic (SPT / ID) 2. Therapeutic 3. R & D
4	Manufacturing	indigenous or imported	indigenous or imported
5	License No: Manufacturing / Import Valid up to Attach authenticated copy of manufacturing license / Free Sale Certificate issued by NRA		
6	Bulk Material:	Imported / Indigenous	Imported / Indigenous
7	Details of manufacturing procedures/steps concerning Tests <ol style="list-style-type: none"> <li>i. Microbiological testing (sterility testing)</li> <li>ii. Protein content by Modified Lowry method<sup>#</sup></li> <li>iii. Protein Profile: SDS-PAGE pattern</li> <li>iv. Biological testing (Skin Prick Test) : Comparison of old vs new batch to be done by the manufacturer</li> </ol>	Provided / Not provided	Provided / Not provided
8	Dispensing / Packing done	Locally / Source Country	Locally / Source Country
9	Relevance of Allergen for Indian patients Bibliography references if available for India.  <i>Allergens for which literature about their Allergenicity on Indian patients is not available but if international / global data is available, may be permitted only for research to generate Indian data.</i>	Provided / Not provided	Provided / Not Provided
10	Storage and Transport conditions	Provided / Not provided	Provided / Not provided
11	List of end users in India (Clinicians/Allergy Centers)	Provided / Not provided	Provided / Not provided

## ALLERGEN PRODUCTS

Checklist for verification of information to be provided by applicant at **CDSCO**

### Additional Information required for in-vivo products

S. No.	Documents Required (In English)	Documents Submitted Yes/No	Comments	Compliance Status
1	<b>Details Of Allergens</b>			
	Common Name			
	Scientific Name (Up To Species Name)			
	A) Single Allergen (Purified /Crude Extract) B) Mixed Allergen (Purified / Crude Extract)			
2	<b>Literature Of Instructions For Use.</b>			
3	<b>Any Other Information</b>			

### Additional Information required for in-vitro products

S. No.	Documents Required (In English)	Documents Submitted Yes/No	Comments	Compliance Status
1	<b>Details Of Coated Allergens</b>			
	Common Name			
	Scientific Name (Up To Species Name)			
	Allergen (S): Single / Multiple/ Mixed			
	<b>In Case Of Multiple Of Mixed Allergens</b> a) Represent Single Kit b) Represent Multiple Kit			
	<b>Nature Of Coated Allergen :</b> a) Crude Extract b) Purified Extract c) Recombinant Product d) Purified Protein			
2	<b>Product To Be Used For :</b> a) Quantification of Total IgE b) Quantification of Allergen Specific IgE c) Component of Kit (Reagents Etc.) d) Equipment / System			
3	<b>Operation Manual or Instructions For Use</b>			
4	<b>Laboratory Test Results Verifying The Product's Specifications.</b>			
5	<b>Intended Use:</b> <ul style="list-style-type: none"> <li>• <b>Diagnostics</b> : SPT/ Patch/ Intradermal</li> <li>• <b>Therapeutic</b> : SCIT</li> <li>• <b>Therapeutic</b> : SLIT</li> <li>• <b>R &amp; D</b></li> </ul>			
6	<b>Any Other Information</b>			